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8 JUN 2017



01 June 2017

## CUSTOMER NOTIFICATION – DC BEAD™ and DC BEAD M1™

Dear Customer

I am writing to let you know that, following receipt of full approval from the British Standards Institution (BSI), DC Bead™ and DC Bead M1™ has now successfully been reclassified as a Class III product. The IFU for the Class III product consolidates DC Bead™ and DC Bead M1™ into a single IFU, along with all the information on the loading with doxorubicin for treatment of Hepatocellular Carcinoma and Irinotecan for the treatment of metastatic Colorectal Cancer. Safety information relating to the drugs are also presented from information in the Summary of Product Characteristics.

As a result current DC Bead product supplies have been accompanied by a Class IIb Instructions for Use (IFU). This letter informs you how you may access the updated IFU.

In considering use of the DC Bead product, please only refer to the updated Class III IFU.

Product Name	Product Code
DC Bead M1™ (70 – 150µm)	DC2V001
DC Bead™ (100 - 300 µm)	DC2V103
DC Bead™ (300 - 500 µm)	DC2V305
DC Bead™ (500 - 700 µm)	DC2V507

BTG have moved from a paper IFU to an electronic IFU (eIFU) for the Class III products. You can find the full Class III DC Bead™ and DC Bead M1™ IFU by visiting the following website and following the simple instructions to download the updated IFU in PDF form: [www.eIFU.btgplc.com](http://www.eIFU.btgplc.com)

Alternatively, if the website is unavailable, you can contact customer services on [customer.services@btgplc.com](mailto:customer.services@btgplc.com) or on one of the following numbers to have a copy of the IFU sent to you within 7 days free of charge. We are happy to supply the IFU in your local language upon request.

Spain +34 911 981 738

Italy +39 069 480 5067

Portugal +351 308 802 698

All other Countries +44 203 318 7881

Germany +49 303 080 9275

France +33 184 884 056

Netherlands +31 202 410 932

If you are a distributor or wholesaler or if you have provided the DC Bead™ and DC Bead M1™ products to any other facilities, please provide this notice to your customers.

If you have any questions or need further information, please contact your local sales representative.

Sincerely,

*N. Ghedia* 01 JUN 2017

Nisha Ghedia

Associate Quality Director

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